OCT 1 8 2001

K013150

UltraGuide Ltd.

510(k) Summary

MR-Guide 2000

I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Tirat Hacarmel Industrial Park
POB 2070
Tirat Hacarmel 30200
Israel

C. Contact Person: Dr. George Myers, 201-727-1703, Fax 201-727-1708

D. Date of preparation: January 2, 2001

II. Device Data

A. Trade Name: UltraGuide MR – Guide 2000

B. Common Name: Guiding System for Interventional Instruments for clinical interventions performed under imaging by magnetic resonance

C. Classification Name: Accessory for System, Nuclear Magnetic Resonance Imaging, 90 LNH, Regulation Number 892.1000

III. Legally marketed predicate devices.

A. MR-Guide 3000, K011418

B. CT-Guide 1010, K002258

IV. Description

The MR-Guide 2000 provides visual guiding information of the interventional instrument by overlaying graphics depicting its relative position and its predicted future path on the MR image of the internal organs all displayed on the monitor of a personal computer.

V. Intended Use

The MR-Guide 2000 system is a frameless stereotactic guiding accessory for Magnetic Resonance (MR) systems. The system is MRI-compatible. It displays the simulated image of a rigid insertion instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the MR image of the target organs and the projected future path of the interventional instrument, compensating for respiratory movements of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where magnetic resonance is currently used for visualizing such structures.

VI. Technological characteristics

The device uses a magnetic tracking system comprising transmitters and sensors, sold under the trade name "MiniBird," to determine the location and orientation of the interventional instrument. This magnetic tracking system has been used on medical devices cleared by the FDA. The position and orientations of the interventional device tool, and the MRI images acquired by the MRI scanner, are transmitted to a data processor (computer), which makes the necessary calculations to provide the guidance graphic overlay depicting the interventional instrument on the MRI image.

VII. Testing

A. Non-clinical tests

The MR-Guide 2000 has undergone extensive bench tests for electrical safety and electromagnetic compatibility to validate all design changes. The major components (the computer and optical tracker) are all commercial devices with published environmental and physical specifications.

Accuracy tests were done in phantoms.

B. Clinical Test

Since this system uses the same technology as the predicate device, a clinical test is not necessary.

VIII. Conclusion

The tests show that the UltraGuide MR-Guide 2000 is equivalent to the predicate devices in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2001

UltraGuide, Ltd.
% George H. Myers, Sc.D.
Medsys Inc.
377 Route 17 South
HASBROUCK HEIGHTS NJ 07601

Re: K013150
Trade/Device Name: UltraGuide MR-Guide 2000, Guilding System for Interventional Instruments
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: July 27, 2001
Received: September 20, 2001

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K013150

Device Name: MR-Guide 2000

Indications for Use:
The MR-Guide 2000 system is a frameless stereotactic guiding accessory for Magnetic Resonance (MR) systems. It displays graphics depicting the position and future path of a rigid interventional instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the MR image of the target organs. MR-Guide 2000 system also enables monitoring the respiratory phase of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where magnetic resonance imaging is currently used for visualizing such structures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use √

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013150